06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Seafood HACCP [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 6/29/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: TBD

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Seafood Hazard Analysis and Critical Control Point

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: William R. Jones

10. Provide an overview of the system: Commercial seafood processors develop their plans of food safety controls to identify and prevent potential health hazards with their products. These controls comprise the processing firm's hazard analysis and critical control point (HACCP) program. CFSAN's Seafood HACCP application provides the means both to capture the controls and to evaluate each processing firm's performance with respect to its HACCP program. FDA field inspectors enter data directly into the Seafood HACCP application through the CFSAN Intranet. Then CFSAN's Office of Food Safety (OFS) evaluates each processing firm's performance in complying with its controls and generates a series of summarized reports. This evaluation process enables OFS management to evaluate the performance of processing firms as well as determine industry trends with respect to compliance and regulatory activities. The Seafood HACCP application also allows OFS to meet the Center's post-market, scientific, and business process goals in the area of seafood safety. HACCP plans are generally protected, and withheld from release subject to FOIA exemption (b)(4). The Seafood HACCP database is accessed through the Intranet. The database and server are protected by logical controls.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system captures firm data.

The Agency performs HACCP compliance inspections of domestic and foreign fish and fishery products processing facilities. These inspections ensure that these processors implement a system of preventive controls, in addition to ensuring compliance with more traditional regulatory requirements, such as the Current Good Manufacturing Practice Regulation. HACCP tracks the implementation of HACCP plans and sanitation controls needed as part of the inspection of the processor's entire HACCP system.

PII in this system is limited to the names of FDA and State inspectors that are included as standard elements of the report forms submitted in the evaluation and approval process.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information is protected by administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: John Simms
Sr. Official for Privacy Approval: Promote
Sr. Official for Privacy Name: Frederick J. Sadler
Sign-off Date: 8/6/2010
Approved for Web Publishing: Yes
Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Medical Safety Network [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/22/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-1020-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: OMB 0910-0471

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDRH Medical Product Safety Network (MedSun)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Marilyn Flack

10. Provide an overview of the system: The Medical Product Safety Network (MedSun) is an Internet-based system. Health-care facilities use MedSun to voluntarily submit reports of adverse events involving medical devices regulated by FDA. Participating facilities include hospitals, nursing homes, outpatient treatment and diagnostic centers and home health agencies. Each facility designates a person(s) to submit these reports. Each reporter is authenticated at the MedSun system web server, and each reporter has access only to their facility's data. This data is transferred in real time to database servers. No data is stored on the website. Submitted data is then analyzed by FDA employees to gain a perspective on postmarket problems with medical devices.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Device identifiers of name of manufacturer, name and model number of the device are shared

with the public so lessons learned about particular devices can be shared. Serial numbers of devices are shared with the mfr and with others in the FDA so regulatory actions may be taken with the mfr. Contact info for the reporter is not shared with the public, but is shared with the mfr and others in FDA so follow-up questions may be directed to the reporter of the problem. No shared information can be traced to a patient.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: MedSun receives information concerning adverse events with medical devices from facilities which participate on a voluntary basis and the designated reporters are trained on what is collected and how to report. FDA collects device identifiers so it knows which mfr and which product is the subject of the report. FDA collects contact information from the reporter so so it may ask follow-up questions about the reported device problem. FDA uses the information to trend problems with devices and to work with mfr to solve the problems with the devices. Reports with all collected information are shared with others in FDA who also work to follow up on the information, and with the device mfr, who are under legal obligation to follow up on each report. FDA shares redacted (only the event description and name of mfr, name and model of the device) reports on a public web site so all may learn about issues. No reporter identifiers are ever shared with the public. No collected or disseminated data can be traced to a patient

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) In 10 years of data collection, we have not altered the PII information collected. To make such a change would require changing the device reporting regulation (CFR 21, part 803). However, if this were ever to occur, each reporter would be contacted and told of the changes and given the opportunity to withdrawal from the program. If they opted to stay in the program, they would sign a new form

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: We meet all mandated administrative, technical, and physical control requirements for a Major Applications

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Stephen Veneruso
Sr. Official for Privacy Approval: Promote
Sr. Official for Privacy Name: Frederick J. Sadler
Sign-off Date: 9/9/2010
Approved for Web Publishing: Yes
Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Internet [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/9/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-02-01-02-1060-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC Internet

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Josh Lehman

10. Provide an overview of the system: This system focuses on the information technology infrastructure to provide a platform for the display of information on FDA's public Internet web site, www.fda.gov. The Office of Public Affairs, Web Site Management Staff, FDA web Content Program Manager, and center/organization content developers have responsibility for the site's specific content management. The site provides a mechanism for FDA staff to post FDA information to the public and to ensure the availability and integrity of that data so that the various FDA content managers can safely and securely provide data to the site.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system consists of the

information displayed on www.fda.gov. The content on the website is public facing, and does not contain any PII. Each application and the associated data visible on www.fda.gov is the responsibility of the FDA Website management staff and center/organizations, which manage the content of those systems and the data being provided to the website. The system is not part of the Infrastructure project.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: John Simms

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Sarah Kotler

Sign-off Date: 6/9/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA Online Reporting Analysis Decision Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 5/24/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-01-1040-00-111-033

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA ORA Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bhabani Das

10. Provide an overview of the system: This is a data warehouse and reporting system developed to provide domestic and import reports to headquarters and field users.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information available in this system can be broken down into different areas.

1. Data that is collected as a result of a product being imported into this country. Basically the type of product and how it is packaged.

2. Data that is collected as a result of sample collections. The data collected includes data such as pac, product, industry, firm name, hours, and operation date.

3. Data that is collected as a result of firm inspections. The data collected includes data such as pac, product, industry, firm name, hours, and operation date.

4. Data that is collected as a result of sample analysis. The data collected includes data such as pac, product, industry, firm name, hours, operation date, and results.

5. Data that is collected as a result of legal actions taken against a firm. The history of the legal action is recorded such as when an action was proposed, when it was sent to legal council, etc.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Bhabani Das

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/2/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Small Business Nutrition Labeling Exemption [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 5/18/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: TBD

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Small Business Nutrition Labeling Exemption (SBNLE)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rene Miguel Amaguana

10. Provide an overview of the system: The Federal Food, Drug, and Cosmetic Act requires packaged foods and dietary supplements to bear nutrition labeling unless they qualify for an exemption. A small business the produces a low-volume product may submit a Small Business Nutrition Labeling Exemption (SBNLE) Notice form stating it qualifies for an exemption from FDA's nutrition labeling requirements.. The exemption applies if the business employs fewer than 100 full-time equivalent employees and fewer than 100,000 units of that product are sold in the United States in a 12 month period. The exemption is not available for products with regard to which a health or nutrition claim is made.

The SBNLE system facilitates this process; it enables FDA to centrally gather information related to companies seeking an exemption.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The SBNLE system contains information submitted by businesses seeking an exemption. To receive an exemption, businesses must submit a form requiring the firm type, name, mailing address, phone number, email address, time period for the exemption, number of employees, volume of product sold, and the name, title, and work phone number for the firm contact person. SBNLE also retrieves information from other FDA systems. It retrieves information from the Field Accomplishments and Compliance Tracking System (FACTS) database to automatically determine a company type (such as manufacturer or importer) based upon their Federal Employer Identification (FEI) number. SBNLE retrieves FDA employee data from the Enterprise Administrative Support Environment (EASE) system to automatically and securely log on authorized users. The only personally identifiable information (PII) collected via the SBNLE system is contact and authorization information for FDA employees involved in the exemption process and contact information for the small business employees involved in requesting an exemption.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information is protected by administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: John Simms

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Sarah Kotler
Sign-off Date: 6/9/2011
Approved for Web Publishing: Yes
Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Food Applications Regulatory Management [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 5/17/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-4050-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CFSAN Food Applications Regulatory Management (FARM)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ziyad, JoAnn

10. Provide an overview of the system: The FARM system is an end-to-end electronic information management system that manages and validates the receipt, processing, storage, routing, tracking, and reporting of food ingredient information collected from the food industry. It manages information regarding food ingredients that are added to or will come in contact with food for human consumption and ingredients that are consumed as dietary supplements. The information that industry submits to the agency contains chemistry, toxicology, environmental, nutritional, microbiological, and other relevant safety-related data. Information collected by the FARM system consists of data required to perform the safety review of food ingredients under the Federal Food Drug and Cosmetic Act, the Dietary Supplement and Health Education Act (DSHEA), the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), and related FDA regulations set out in the Code of Federal Regulations at 21 CFR 71 and 170-190. These legal authorities describe the data required from industry for the Food and Color Additive Petitions, Food Contact Notifications (FCN), Generally Recognized as Safe Notices (GRN), New Protein Consultations, Bioengineered Foods Consultations (BNF) for the Office of Food Additive Safety, New Dietary Ingredient 75 Day Notices, and 30 Day Structure Function Label Notices for the Office of Nutrition, Labeling and Dietary Supplements. All petitions, notices, and notifications must contain appropriate and sufficient scientific data and information to support the safety review process.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The FARM system contains information submitted by the food industry on ingredients that are added to or will come in contact with food. All petitions, notices, and notifications must contain appropriate and sufficient scientific data and information to support the safety review process.

The FARM system contains a minimal amount of PII which is required in order to contact industry business personnel. The names and business phone numbers collected are not used to retrieve information from the FARM system. The agency collects only the information provided for under the Federal Food, Drug and Cosmetic Act (FFDCA) and corresponding regulations (21 CFR 71-199), the Dietary Supplement and Health Education Act (DSHEA), and the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: John Simms

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler
Sign-off Date: 5/17/2011
Approved for Web Publishing: Yes
Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Shellfish Shippers [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 5/13/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: TBD

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Shellfish Shippers

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kevin Smith

10. Provide an overview of the system: FDA and State regulatory agencies, foreign nations, and the molluscan shellfish industry participate in the National Shellfish Sanitation Program (NSSP). Each participant identifies its certified shellfish processors to FDA on Form FDA 3038, the Interstate Shellfish Dealer's Certificate. FDA uses this information to compile the Interstate Certified Shellfish Shippers List, (ICSSL) a monthly publication that lists certified shellfish processors. This list is used to identify and exclude shellfish processed by uncertified processors.

FDA's Shellfish Shippers System has an online electronic data submission component that enables the State Control Authority (SCA), Shellfish Shipper inspectors and administrators to securely submit FDA form 3038 directly via the Internet. Submitters also have the option to provide a hard copy form 3038 to the FDA.

FDA maintains the form 3038 Certificate information in a centralized CFSAN (Center for Food Safety and Applied Nutrition) database. After the CFSAN Shellfish Shippers Administrator reviews and approves the submitted Certificate data, the Certificate information is entered into the system database and the certification information is made available to the public on the ICSSL.

The ICSSL displays: certified shellfish business name, city/town, state/country, and business's shellfish function (e.g., reshipper, shucker-packer); a list of FDA regional offices with contact names, office address, office phone and fax numbers, office email; and, State and country shellfish regulatory official contact information including the name of the official, title, office address, office phone and fax number, and office email address.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects shellfish industry firm data and certification information as part of FDA Form 3038 submitted by the firms. This information includes the business contact information for the certified shellfish entity, inspection date, certificate number and date of certification, state inspector name, SCA designee name, and the date of submission to FDA. This information is used by food control officials, seafood industry and other interested persons and is published monthly in the ICSSL, a primary tool for authorities to differentiate between certified and uncertified shellfish processors. The personal information collected in the system is a required element of form 3038 and does not include any PII beyond the names and titles of the state inspectors and SCA or SCA designee.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information is protected by administrative, physical, and technical controls in accordance with policies and regulations from

the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within the system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: John Simms

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 5/17/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA MARCS Compliance Management Services (CMS) [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 5/12/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-08-01-0202-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-10-0010 Bioresearch Monitoring Information System, HHS/FDA

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Mission Accomplishment and Regulatory Compliance Services - Compliance Management System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kelemework Yimam

10. Provide an overview of the system: The MARCS-CMS is a web-based search and retrieval system that provides the ability for Field and Center Compliance Officers to create a Compliance Action via FACTS or independently of FACTS and electronically send Compliance Actions to the Centers or directly to OGC for review. The Centers' Compliance, other organizational and regulatory components, and its field staff use this information in the preparation of business process responses and/or actions. Some of the MARCS-CMS data for bioresearch monitoring is protected by the Privacy Act of 1974. 5 USC 552A, as Amended. 5252a. MARCS-CMS also includes data which is subject to protection under the FOIA (5 USC 552, as amended). MARCS-CMS includes predecisional & deliberative materials, drafts, etc., which are protected under Exemption (b)(5) of the FOIA, for inter- and intra-agency memoranda, and open investigatory records, subject to withholding under exemption 7 of the FOIA.

ORA and all Centers are using MARCS-CMS to increase integration of their regulatory work and reduce costs of system development and operation. It provides access to Field, Center, and other ORA regulatory components' officers and managers. An Enterprise Search component assists searching within the MARCS-CMS document repository. Through MARCS-CMS all users can obtain reference information from public sources, such as the Federal Register, and regulatory material related to a particular food safety or compliance issue. The MARCS-CMS incorporates regulatory information from other Centers including CDER, CBER, CFSAN, CVM, CTP, CDRH, and ORA.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This

question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: MARCS-CMS contains inspection and investigative records, sample collection reports, analytical worksheets, open investigatory files and other records supporting FDA's administrative and legal actions, including Warning Letters and Untitled Letters. Such CMS data contains PII in the form of names of clinical research investigators and their related identifying information. In some instances the business entity or firm name is the clinical research investigator's name, such as a sole proprietorship operated by the clinical research investigator. CMS files may also contain PII in the form of individual consumer names when referenced in consumer complaints or in medical records obtained during FDA inspections, investigations or other legal and administrative actions. These CMS records are used in support of FDA's efforts to track clinical research investigators, monitor complaints submitted to FDA, and in support of FDA inspections and related administrative or legal actions. Clinical research investigator names and identifiers are typically provided voluntarily or on occasion by demand of FDA. Consumer names are voluntarily provided directly to FDA or gathered as part of FDA inspections or investigations. Because this system contains individual names and personal identifiers, access to it is strictly controlled.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within MARCS-CMS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within MARCS-CMS.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: George Brush

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/8/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA Firms Master List Services

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 5/11/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Firm Master List System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chris Cross

10. Provide an overview of the system: The Firms Master List Services (FMLS) system is organizationally located within FDA's Office of Regulatory Affairs (ORA). The system provides a uniform method for accessing and maintaining firm (e.g., regulated food establishments) data across the ORA. The purpose of FMLS is to:

(1) provide services at near real time operation due to the mission critical 24/7 nature of ORA's business and the importance of maintaining the accuracy of continuously changing firm data;

(2) provide a set of services for validating and matching firm data that may be used throughout the FDA;

(3) provide mechanisms for adding, updating, merging and unmerging firm data as well as functionality to change, add and update food firm data such as firm ownership, physical location and registration information; and

(4) adhere to industry standards for Web Services in order to integrate the address validation and matching services with other FDA/ORA applications and to facilitate compliance with any future FDA Service Oriented Architecture (SOA) standards.

The FMLS system has five main components:

1. The Address Validation Web Service (AVWS v1.2) provides service consumers with the capability to validate the addresses and provide geocode information for firm records. The Address Validation Web Service uses the data quality tool, DataFlux, for address validation. The Google Geocode Service is used for the geocoding capabilities. The consumers for AVWS are the Device Registration and Listing Module (DRLM), FDA Unified Registration and Listing

System (FURLS), Food Facility Registration Module (FFRM), Firms Management System (FMS) and Automated Commercial System (ACS) Encrypted Social Security (ESS) Update external applications.

2. The Match Web Service (MWS v1.0) provides service consumers search functionality for existing firms records in the Firm Master List (FML) database. The Match WS uses the data quality tool, DataFlux, to generate match codes used for matching in FML database. The consumers for MWS are Prior Notice System Interface (PNSI), Prior Notice (PN) PNACS and FMS external applications.

3. DataFlux is the new state of the art Data Quality tool acquired by the FDA to maintain firms data quality.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information FDA collects, maintains and disseminates via the FMLS system includes Firm Name, Physical and/or Mailing Address, Firm Contact Information, Food Facility Registration, Cross Reference to another FDA Identifier, such as data universal numbering system (DUNS) number or another FDA Establishment Identifier (FEI). The data maintained within FMLS, together with the system capabilities enable FDA to provide a set of services to FDA's internal and external system consumers for firm address validation, firm matching, adding, updating, validating, merging and unmerging firm data including food firm ownership changes and registration status changes.

The FMLS system is not intended to collect PII and does not require or solicit PII. Personally identifiable information such as the name, work mailing address, work telephone number, and

work email address for the firm employee designated as the contact person may be submitted to FMLS voluntarily as part of the contact information for the firm registration if the firm chooses to have a personal contact listed. FMLS does not collect or store any PII other than voluntarily provided firm contact information. Firms may withdraw or amend this contact information at any time. FMLS is a back-end system, and use of FMLS is not mandatory for any users (physical persons). FMLS is used by systems and provides backed interfaces to the consumer systems listed in item 10.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Agnes Kivuvani

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Sarah Kotler

Sign-off Date: 6/9/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA MARCS Interface [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 5/11/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-08-01-0202-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA ORA Mission Accomplishment and Regulatory Compliance Services (MARCS) Interface (MI)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tina Nguyen

10. Provide an overview of the system: The Office of Regulatory Affairs (ORA) Mission Accomplishment and Regulatory Compliance Services (MARCS) Interface (MI) is a multi-phased effort that will use Oracle Application Development Framework (ADF) software and other Oracle Fusion Middleware technologies to create an environment where users can, with a single sign-on (SSO), access multiple FDA systems. When fully implemented, the interface will provide:

A web infrastructure that will support new applications under development at ORA, and a platform for integrating older applications as they are migrated, or reengineered, into a web environment.

A number of standard services as a part of its environment including workflow, personalization, secure role-based access to systems, Public Key Infrastructure (PKI) integration through the Agency's SSO and Active Directory (AD) Servers, content indexing and retrieval, and other standard web application features.

Process flow capability that will support import review functionality, allowing import reviewers to retrieve data from multiple databases without the manual processes and cumbersome use of legacy applications that are now required.

A comprehensive user environment for information management, allowing retrieval of data from all ORA systems, ORA Reporting, Analysis and Decision Support System (ORADSS) and Automated Laboratory Management (ALM).

An environment tailored to the ORA work community's information needs. The environment can easily be customized to each user's role, providing links to supporting systems, websites, and any FDA information needed to support each user's daily information needs.

The MARCS Interface will serve as the access control gateway for all ORA applications.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The ORA MARCS Interface will not collect or maintain data except for the minimum needed to establish a secure account ID. Data accessed through the interface may include:

Data about the facilities that manufacture, store, process, or ship FDA regulated products into the US.

Data about importers, consignees, shippers, carriers, involved in importing and/or distributing imported FDA regulated products.

Data about the size, contents, type of FDA regulated products entering the US.

Data regarding inspections, reviews, investigations or past history (including recalls) of FDA regulated products entering the US, and entities involved in their manufacture, processing, labeling, shipping or other regulated role .

FDA approved standards for FDA regulated products.

Most of this data already exists in FDA legacy systems and is currently used in processes employed to review admissibility of imported foods, drugs, medical devices, and other regulated products.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g.,

disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: George Brush

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/2/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA Quality Management Information System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 5/11/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Quality Management Information System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Cathy Burns

10. Provide an overview of the system: The Office of Regulatory Affairs (ORA) Quality Management Information System (QMIS) supports the ORA Quality Management System including ORA laboratory accreditation in defining, tracking, understanding, and continually improving processes and methods. QMIS will support document control, corrective actions, complaints, and record control.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: QMIS is not intended to collect, and does not require or solicit personally identifiable information (PII). QMIS does not contain PII.

QMIS is a document control and management system serving all FDA ORA Offices for core business processes:

QMS-1: Document Control and Management

The Document Control workflow includes recommending, processing, reviewing, approving, and automated routing of new and changed documents. The scope encompasses standard operating procedures (SOPs), policies, and other directives governing the way the agency does business. The procedure also covers storage of final documents, maintenance of active document lists and master lists, and providing search tools for documents. Forms and evidence generated during quality management activities are covered under Record Control.

QMS-2: Control of Records

This procedure applies to the control and management of information and collateral evidence collected or generated during quality management activities such as product reports and management reports. The information is stored and retrieved to provide evidence of system performance and effectiveness to assure that records are properly managed. Records include reports, correspondence, quality records and technical records. Quality records include the following: internal audit reports, management reviews, corrective and preventive actions. Technical records include completed forms and reports.

QMS-3: Management Review

Top management conducts planned reviews of the quality system events and trends to ensure the continuing suitability, adequacy, and effectiveness, of the quality system in achieving the stated quality objectives and to ensure continuous improvement. From this analysis, an action plan is developed, implemented and monitored. Action items identified in the action plan are carried out using the corrective action procedure or preventive action procedure as appropriate.

QMS-4: Audits

Scheduled independent audits are performed to ensure compliance of practice with documents and effectiveness of results in achieving quality system goals.

QMS-5: Control of Nonconforming Processes, Services, and Products

This procedure applies to responses to nonconformities (NCs) and the practices to be followed to detect, identify and trend them. Nonconformity is defined as a departure of a quality characteristic from its intended level. Both frequency of occurrence and severity level may determine if a nonconformity or pattern of repeated nonconformities merits a corrective action. On-the-spot or immediate corrections of noncritical NCs are simply logged for historical purposes and can be annotated on the worksheet, report, memo, or similar document.

QMS-6: Continual Improvement

This procedure communicates the process that involves ORA customers and staff in the identification, design, development, and implementation of strategic and operational initiatives necessary to achieve the organization's mission: "Protecting and Promoting Public Health." This procedure defines the general methods to be followed to define goals and measure results. It will assist users to identify potential QMS improvements that may be gained through process changes, corrections or improvements. The procedure does not require a corrective action to trigger activity. It may lead to a preventive action or a workflow change that will improve staff productivity.

QMS-7: Corrective Action

This procedure establishes the process to identify, track, trend, and complete the investigation of the non-conformance, and correct the causes of existing non-conformances including complaints in processes, services, products, and the Quality Management System. The cornerstone of corrective actions is written and retrievable documentation of actions taken and follow-up monitoring to determine that corrective actions have been performed, documented and effective.

QMS-8: Preventive Action

Preventi

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Cathy Burns

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 5/16/2011
Approved for Web Publishing: Yes
Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Traction [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 3/10/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

7. System Name (Align with system Item name): CDRH Traction

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Paul Fisher

10. Provide an overview of the system: Traction is a collaborative tool which stores all text-based information in a database file providing a place to create and share documents or data which is called a journal. The journal is a SQL-based database which is managed using commands developed by the vendor, Traction Software. These commands are included in the Traction install package and are executed by a local FDA Traction System Administrator when maintenance is needed. Database maintenance is not needed on a regular basis. All non-text based data (documents, spreadsheets, attachments) is stored directly on the host server and can be accessed at a server level.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Traction is a collaborative tool which stores all text-based information in a database file providing a place to create and share documents or data which is called a journal. The journal is a SQL-based database which is managed using commands developed by the vendor, Traction Software. These commands are included in the Traction install package and are executed by a local FDA Traction System Administrator when maintenance is needed. Database maintenance is not needed on a regular basis.All non-text based data (documents, spreadsheets, attachments) is stored directly on the host server and can be accessed at a server level.

Once a user has logged into the application, they will navigate to their team/department's workspace. At this time, they can choose to create a new article (similar to email in composition), comment on an article (continuing a conversation), or upload documents to the shared folders portion of their workspace. As new content is added, the journal will be updated with new content and links to documents which are stored in the application. Traction does not contain PII and no PII is voluntary or mandatory for submission to the Traction tool.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Appplicable

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Frederick Sadler

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 4/5/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Resource Reporting System Via Project [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/9/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-0202-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CFSAN Resource Reporting System Via Project (RSVP)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Charles Sabatos

10. Provide an overview of the system: RSVP is a user-friendly time reporting system that provides data concerning personnel resources planned and expended to support the business processes of the Center for Food Safety and Applied Nutrition (CFSAN) offices and divisions. The application supports over 1200 users and is accessed only through the CFSAN Intranet.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: RSVP does not collect,

maintain, or disseminate any PII and users do not submit any personal information. RSVP only collects the total number of hours worked or on leave for each employee per pay period. Users can only access their own pay period totals in order to allocate hours to the specific projects they worked on. CFSAN uses this information for personnel resource tracking and planning.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 3/17/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA On-line Program Analysis System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 2/28/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-08-01-0201-00-301-092

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA ORA Online Program Analysis System (OPAS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bhabani Das

10. Provide an overview of the system: The On-line Program Analysis System (OPAS) is a planning and analysis tool that provides the Division of Planning, Evaluation and Management (DPEM) data necessary to respond to special requests for information from Congress, Government agencies, and the public. The information collected and consolidated in OPAS includes work plan information and summary data provided by various FDA field activities.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: OPAS contains employee accomplishment information extracted from the ORA Field Accomplishments and Compliance Tracking System (FACTS). The extracted information refers to the employee's work activities by Operation, Firm, Location, Position Class, Program Code, and Number of Hours. The only information gathered from the employee is a system-generated key called PERSON ID. The key is used to identify the number of employees who are involved in various activities. This information is then counted and aggregated for each dimension (Operation, Location, Position Class, Program Code, Fiscal Year). Values are loaded into a Microsoft Analysis Services multi-dimensional database for display to the OPAS users (Headquarters managers and analysts, and field managers).

Work plan information in OPAS is collected from the PLAN_MODEL table in the Field Workforce Planning System (FWFPS). This table stores only the number of employees (head counts). It does not contain data related to any individual employee. OPAS does not display public information (i.e., names of Firms). Although this information is collected in FACTS, OPAS displays only counts of Firms in various categories (by Establishment Type, Industry Code, Location, and Fiscal Year). DPEM uses the information in OPAS to support data findings and decisions in its responses to requests.

OPAS does not collect, maintain or disseminate personally identifiable information (PII).

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Bhabani Das

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 3/3/2011

Approved for Web Publishing: Yes
Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Color Certification [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 2/18/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-0505-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: OMB 0910-0216 (Exp. 2/28/2011)

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CFSAN Colors Certification System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adam Rixey

10. Provide an overview of the system: The Colors Certification System supports batch certification of color additives in accordance with CFR Title 21, Parts 70, 74, 80, and 82. Colors Certification data is exported to the CFSAN web servers so that twenty-one industrial users may view data on their own certification requests (the remaining eleven requestors certify only one or two samples per year and have not chosen to participate in the online system at this time). Requestors for color certification will have access only to their own data on a separate public web site. All other data is restricted to the Office of Cosmetics and Colors.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected is necessary to ensure the name and location of the color manufacturer, where the color additive is being stored, and how the color was made.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 2/25/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Priority-Based Assessment of Food Additives [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 2/18/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-0505-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CFSAN Priority-Based Assessment of Food Additives (PAFA)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mary LaVecchia

10. Provide an overview of the system: PAFA gathers administrative, chemical, and toxicological information on over 3000 food substances directly added to food. In addition, limited information is collected on approximately 3500 food additives that may migrate into food through packaging or the like. This information is used as background material for regulatory review, research projects, and serves to answer Freedom of Information requests in an efficient manner. PAFA data is used to seed the tools used for preliminary Structure Activity Relationship (SAR) analysis when new substances are submitted to the Agency for approval.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: PAFA is used to maintain administrative, chemical, and toxicological information on over 2000 of approximately 3000 substances directly added to food, including substances regulated by the U.S. Food and Drug Administration (FDA) as direct, "secondary" direct, and color additives, and Generally Recognized As Safe (GRAS) and prior-sanctioned substances so that toxicological profiles can be produced for the ingredients added to the food supply. It is a source of information for post-market surveillance of food additives.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 2/25/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Mammography Program Reporting Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 2/17/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-4060-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-10-0019

5. OMB Information Collection Approval Number: OMB 0910-0309

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDRH Mammography Program Reporting and Information System (MPRIS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Timothy Haran

10. Provide an overview of the system: Under the Mammography Quality Standards Act, all mammography facilities must be accredited by an approved accreditation body; certified by the FDA; inspected annually in order to legally provide mammography services in the United States; and facility medical personnel must meet qualification standards. MPRIS is used to schedule and hold reports of inspections, and provides inspection results to CMS.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The information collected identifies the name and physical location of the mammography facility, along with the facility mailing address, telephone and facsimile numbers, the types and number of mammography equipment in use, and the names and qualifications of facility medical personnel, including official contacts for accreditation, billing, and compliance matters.

This information is not considered to be personal privacy information since it is required by, and solely used in keeping with, the provisions of the MQSA and 21 CFR Part 900, that is, in order to contact the regulated facility regarding FDA matters, to determine their certification status, to schedule inspections, and to determine the compliance of the facility and facility personnel with MQSA law and regulations.

The only information collected by the DMQRP regarding MQSA-certified State inspectors is their name, office address, email address and office telephone and facsimile numbers. This is the minimum information about the inspectors necessary to provide them technical, equipment, and policy guidance support. This is public information.

The System of Records: 09-10-0019, "Mammography Quality Standards Act (MQSA) Inspector Profile System, HHS/FDA/CDRH" (formerly the "Mammography Quality Standards Act (MQSA) Training Records") is no longer in use at FDA, and all computerized records that this system was used to collect have been purged from the system. The responsibilities for MQSA inspector audits, evaluations of the inspector's field performance, and inspector continuing education, have been transferred to the Division of State-Federal Relations, in the FDA Office of Regulatory Affairs. The only information collected by the DMQRP regarding MQSA-certified inspectors is their name, office address, email address and office telephone and facsimile numbers. This is the minimum information about the inspectors necessary to provide them technical, equipment, and policy guidance support.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within MPRIS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within MPRIS.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: John R. Dyer

Sign-off Date: 8/22/2008

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDER Special Products Online Tracking System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 1/31/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-020200110 246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Special Products Online Tracking System (SPOTS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Folkendt

10. Provide an overview of the system: SPOTS is a web application which supports the tracking of all ingredients (active or inactive with certain specific exceptions) derived from plant (except highly purified compounds), animal, microorganism and recombinant technology used in pharmaceutical products that are the subject of a CDER NDA, ANDA, or IND.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The SPOTS application is

used by the drug product quality review staff primarily located in the Office of New Drug Quality Assessment (ONDQA), Office of Biotechnology Products (OBP), and the Office of Generic Products (OGD). All three offices are located under the Office of Pharmaceutical Science (OPS). The Office of New Drug Quality Assessment is the Business owner and administrator for this system.

The SPOTS application primary role is a database used to track applications that contain, or use as part of the manufacture, animal-derived, plant-derived, or biotech-generated ingredients. The reviewers add to the database as they review applications that meet the SPOTS criteria. The application also generates reports on an as needed based.

All Product Quality Users are given CREATE (i.e., data entry) privileges. Before the new data is committed, it must first be reviewed by an administrator. Other CDER users are given Search only access. No personnel outside of CDER have access to the SPOTS system. The SPOTS system does not contain PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joe Albaugh (Acting)

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/8/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Financial Reporting System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: Significant System Management Changes

1. Date of this Submission: 1/27/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): In development

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC Financial Reporting System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Amy Kramer

10. Provide an overview of the system: FRS is a logical grouping of two legacy Office of Financial Management (OFM) databases—Asset Management System (AMS) and Central Accounting System (CAS)—with one operational application named Hyperion. Hyperion is a business performance management product from Oracle. Hyperion receives regular data extracts from the HHS Unified Financial Management System (UFMS) as well as the Accounting for Pay System (AFPS) and uses this data for budgeting, forecasting, and business intelligence process support.

AMS and CAS previously were operational FDA applications which served OFM business processes. Both applications have since been replaced by HHS Department-wide applications. AMS was replaced by the Property Management Information System (PMIS), and CAS was replaced by the Unified Financial Management System (UFMS). While the applications have migrated to the Department level, the respective static databases have remained in OFM for reporting purposes. As financial systems, the data will be retained for the proper amount of time.

CAS was FDA's core accounting system and handled all budgeting for FDA offices. In this capacity, CAS tracked payables and receivables relating to contracts between FDA and third parties providing goods and services. AMS was designed to track and manage all FDA accountable property, which is defined as all property valued over $5000. The AMS application was retired in August 2009. The legacy AMS database is the only FRS component which contains PII (the employee badge number). Only two persons have access to this retired database, and the PII has not been provided since the application retired.

This PIA is being updated (1/27/2011) due to the addition of the Business Intelligence Reporting System (BIRS) to the FRS umbrella. The FRS-BIRS system is a data warehousing and Business Intelligence solution. It is used to analyze, aggregate, and summarize the information from one to many transactional business management systems. The system was developed by FDA but will be maintained by ISMS/DESOM/FESM. Initial implementation will have one defined source to the data warehouse – UFMS. The scope of the project includes a user base that will include all of the FDA Office of Financial Management, as well as Budget and Finance resources in each of the Centers of the FDA. Initial licensing of the project limits the user base at 50. However, deployment of the solution across the entire FDA Budget and Finance community may increase the number of users to 100. Future implementations include deployment to other OPDIVs.

Currently, the BIRS component of FRS is hosted at the Center for Information Technology/National Institutes of Health (CIT/NIH). In the past few months, the Hyperion component of FRS migrated to the Contractor Hosted Datacenter in Ashburn, VA. The CAS and AMS components migrated to the FDA White Oak Datacenter.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Federal employee names and employee numbers are stored in the Asset Management System (AMS) legacy database, which is a component of the FDA Financial Reporting System (FRS). The information enables the assignment of responsible employee names and numbers to each item of FDA personal property stored in AMS. The information is needed in AMS for property searches in conjunction with periodic equipment inventories.

Hyperion and the CAS database contain financial management, planning, and accounting information about FDA offices, not individual persons.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Only information relating to employees is used.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within FRS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within FRS.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joe Albaugh

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 6/15/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA Open Mentoring

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/26/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Open Mentoring

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jill Sooter

10. Provide an overview of the system: Open Mentoring is a social learning management system that facilitates the knowledge exchange process through intentional networking. It allows ORA to match, manage and measure one-to-one, group and situational mentoring relationships built around customized learning projects and objectives. Open Mentoring helps ORA preserve its intellectual capital and supports Division of Human Resource Development (DHRD) in its mission to to provide high-quality learning opportunities through the delivery of timely and cost effective learning products that support the mission and strategic goals of the FDA and that meet the training and development needs of ORA personnel, state and local regulatory officials, and other stakeholders.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system maintains mentoring information. It will porovide senior ORA staff with an open fourm to transfer mentoring knowledge to younger, less experienced ORA staff. Open Mentoring will create a differentiated mentoring database system to fit the unique needs of the ORA user. There will be preparation of lesson plans, objectives, presentations, exercises and assessment tools for training ORA Mentors and Mentees. It will also include preparing, administering and recording webinars. It does not contain or collect any type of PII data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Nipa Shah

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 2/25/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CTP Menthol Document Analysis Tool

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/4/2011

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Menthol Document Analysis Tool

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Deborah Sholtes

10. Provide an overview of the system: This tool is a document management, search, retrieval, cataloging, indexing, and analysis tool for menthol tobacco documents submitted by the tobacco industry. The contractor will use a file server, a database, a search engine, and a web interface as an integrated tool within an enhanced security intranet environment. The tool will fulfill the need to code and abstract 400 GB of documents on menthol cigarettes provided by the tobacco industry. The tool will allow CTP Office of Science and the Tobacco Products Scientific Advisory Committee (TPSAC) to meet it's obligation under Section 907 (e) of the Family Smoking Prevention and Tobacco Control Act to provide recommendations on menthol cigarettes no later than March 23, 2011.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This tool is a document management, search, retrieval, cataloging, indexing, and analysis tool for menthol tobacco documents submitted by the tobacco industry. These documents include information on tobacco firm processes for manufacturing, marketing, and researching mentholated tobacco products. The tool will fulfill the need to code and abstract 400 GB of documents on menthol cigarettes provided by the tobacco industry. The tool will allow CTP Office of Science and the Tobacco Products Scientific Advisory Committee (TPSAC) to meet it's obligation under Section 907 (e) of the Family Smoking Prevention and Tobacco Control Act to provide recommendations on menthol cigarettes no later than March 23, 2011.

The information contained in the system is not related to individuals. There is no personally identifiable information collected, maintained or disseminated by this system. The information within the system is limited to tobacco products and tobacco firm processes.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Deborah Sholtes

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 1/4/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDER Legacy Refresh Systems

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 11/16/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDER Legacy Refresh Systems

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tiffany Lovelace

10. Provide an overview of the system: In July of 2009, DARRTS 3.0 (NDA and ANDA tracking) was rolled out. Some COMIS tracking systems were absorbed into DARRTS, some were retired, and some continued to operate as before, but were upgraded to an Oracle 10g platform running on a Solaris in UNIX. The latter systems, 15 in number, are collectively referred to as LX. These systems track such information as products, advertising submissions, registration and listing, site inspections, and flow of volumes to drug reviewers.

LX includes the systems listed below.

Group One: Systems with access control based network account and Active Directory status, using User Access table records (not Oracle roles) to control level of access

ADMIS – Advertising Management Information System

BrMIS – Bioresearch Monitoring Information System

DADS – Developers and Distributors System

DPRF – Drug Product Registration and Filing

DQRS – Drug Quality Registration System

DRLS – Drug Registration and Listing System

GC – General Counsel Tracking System

INVAS – IND/NDA Volume Accountability System

MACMIS – [DDMAC] Correspondence Management Information System

MEDEX – Medwatch Expedited Reporting Tracking System

User FLX – User FLX Tracking System

Group Two: Systems with access control based on individual Oracle account, using Oracle roles to control level of access

CIS – Clinical Investigator System

INVAS-OC -- IND/NDA Volume Accountability System for the Office of Compliance

PATEXCL – Patent and Exclusivity Tracking System

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CDER LX does not store, process or collect PII.

In July of 2009, DARRTS 3.0 (NDA and ANDA tracking) was rolled out. Some COMIS tracking systems were absorbed into DARRTS, some were retired, and some continued to operate as before, but were upgraded to an Oracle 10g platform running on a Solaris in UNIX. The latter systems, 15 in number, are collectively referred to as LX. These systems track such information as products, advertising submissions, registration and listing, site inspections, and flow of volumes to drug reviewers.

LX includes the systems listed below.

Group One: Systems with access control based network account and Active Directory status, using User Access table records (not Oracle roles) to control level of access

ADMIS – Advertising Management Information System

BrMIS – Bioresearch Monitoring Information System

DADS – Developers and Distributors System

DPRF – Drug Product Registration and Filing

DQRS – Drug Quality Registration System

DRLS – Drug Registration and Listing System

GC – General Counsel Tracking System

INVAS – IND/NDA Volume Accountability System

MACMIS – [DDMAC] Correspondence Management Information System

MEDEX – Medwatch Expedited Reporting Tracking System

User FLX – User FLX Tracking System

Group Two: Systems with access control based on individual Oracle account, using Oracle roles to control level of access

CIS – Clinical Investigator System

INVAS-OC -- IND/NDA Volume Accountability System for the Office of Compliance

PATEXCL – Patent and Exclusivity Tracking System

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval:

PIA Reviewer Name: Joe Albaugh

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 1/5/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Center Electronic Submissions [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/9/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-5030-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDRH Center Electronic Submissions (CeSub)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Paul Fisher

10. Provide an overview of the system: Under the Medical Device Amendments of 1976, manufacturers of medical devices--including but not limited to x-ray machines, pace makers and breast implants--are required to submit applications to the FDA for approval to ensure that these products are safe, effective, and labeled properly before they become available on the market.

CDRH receives and reviews thousands of submissions from regulated industry and consumers seeking FDA approval to market new devices and products, as well as to track changes and adverse events related to approved products. These submissions traditionally have been scanned into the electronic document management system "Image 2000". The CeSub project is based mostly upon the Image 2000 knowledge and document management system, and it adds functionality to permit the receipt and review of electronic submissions.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Under the 1976 medical device amendments to the Food, Drug, and Cosmetic act, the Food and Drug Administration is mandated to collect and analyze manufacturer data related to the safety and efficacy of medical devices before they may be marketed in the US. The information contained in CeSub represents the official record of submissions from manufacturers. This includes Premarket Notifications 510(k), Premarket Approvals (PMAs), Investigational Device Exemptions (IDEs), labeling data, medical device reporting, and establishment registration and medical device listing forms. In addition, all FDA decision letters and any supplemental information requested from the manufacturer are stored in the CeSUB Image 2000 repository. Any IIF data within the system pertains only to the manufacturer submitting the information, and not to patients.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes currently in place.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within (CeSub)/Image 2000 is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within (CeSub)/Image 2000.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/9/2010
Approved for Web Publishing: Yes
Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDRH Center Tracking System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/9/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-09-02-0513-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDRH Center Tracking System (CTS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Paul Fisher

10. Provide an overview of the system: The Center Tracking System (CTS) is a workflow, work management, and tracking system which supports a variety of pre-market and post-market business processes in the Center for Devices and Radiological Health.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CTS is a web based application for workload management and tracking, which contains information related to the pre-market submission review process. Specific activities or processes currently supported by

CTS include Premarket Division Tracking, CLIAs, RFDs, COATS, DNMS, 522 Studies, COPS and eConsults.

Information about devices that have successfully completed any required pre-market review by the FDA is made public through the CDRH and FDA Freedom of Information Act (FOIA) Offices. Information about devices that are under review, or which were not approved, is not shared. The business contact information in CTS is also not published, but can be made available under a Freedom of Information (FOI) request.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/9/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDER Electronic Listing [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 9/8/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDER Electronic Drug Registration and Listing

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Julieann Dubeau

10. Provide an overview of the system: SPLs are received via the FDA Gateway. A process moves the SPL from the Gateway holding area to the SPL Staging Area Inbox. The eLIST system polls the INBOX for new submissions and attempts to upload them. If the submission passes all validation rules, the SPL is stored in the repository and the data parsed into Oracle tables. If the submission fails one or more validation rules, the system produces a validation report and stores it as well as a copy of the SPL in the SPL Staging Area Outbox. When the marketing date for an SPL is reached, the system redacts and packages the SPL for transmission to the National Library of Medicine (NLM). These files are also stored in the SPL Staging Area Outbox.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: eLIST serves as a central data holding place for drug registration and listing. The information collected including manufacturer, registration information including register number, FEI number, company name and address etc. and drug listing information include ingredients of the drug, package of the drug, and the usage of the drug.

The information collected will be used for the purpose of validation and the purpose of drug label publish (to the public)

The information are collected by mandate.

The vendor point of contact information is redacted from the system before it goes to the public.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/8/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDER Document Archiving, Reporting, and Regulatory Tracking System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/8/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-020200110 246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDER Document Archiving, Reporting and Regulatory tracking System (DARRTS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Julieann Dubeau

10. Provide an overview of the system: CDER is responsible for tracking, reporting, and maintaining an archival record of the drug and biological products submitted to the FDA for review. The center reports to Congress on a number of issues, including performance on Prescription Drug User Fee Act of 1992 (PDUFA) related goals. To fulfill the mission and goals of CDER, DARRTS will provide a flexible, integrated, web-based system that will:

• Support the drug review and biologic review product tracking process;

• Provide administrative and regulatory reporting capabilities; and

• Improve the process by removing design components that result in work-arounds in the current system.

DARRTS is a component of CDER's overall initiative to move toward a fully electronic submission receipt, processing, and management system. DARRTS, which will be implemented in phases, will replace CDER's current systems supporting the receipt, management, and reporting of information about clinical investigational and marketing submissions for human drugs and therapeutics.

According to NIST SP 800-18, DARRTS is considered a Major Application (MA). Major Applications (MAs) are systems that perform clearly defined functions for which there are readily identifiable security considerations and needs.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): DARRTS shares information with other operating divisions within FDA to facilitate the receipt, management, and reporting of information about clinical investigational and marketing submissions for human drugs and therapeutics. The information is business data only (not personal).

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: DARRTS will replace CDER's current systems supporting the receipt, management, and reporting of information about clinical investigational and marketing submissions for human drugs and therapeutics. The email collected and dissimenated is for submission of firm information or for a company representative in the line of duty.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes currently in place.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within DARRTS is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within DARRTS.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis
Sr. Official for Privacy Approval: Promote
Sr. Official for Privacy Name: Frederick J. Sadler
Sign-off Date: 9/8/2010
Approved for Web Publishing: Yes
Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Mail [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 9/8/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC Mail

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Neubauer

10. Provide an overview of the system: The FDA's e-mail system has evolved into a core service and is a vital component integrated into the FDA's regulatory mission and records management systems. However, significant challenges exist in supporting the agency's current FDAHHSMail system. Demands for increased customer service and responsiveness, anticipated user growth, rapid changes in technologies, and increased security threats mandate the deployment and management of a new, scalable, and highly secure e-mail environment. A top priority for the FDA is to gain full control of its internal e-mail operation and transform the current messaging system to a solution based on Microsoft Exchange 2007.

The FDA has outgrown its current enterprise Exchange 2003 e-mail and archiving infrastructure and plans to migrate its users to Exchange 2007 and an archiving solution compatible with Microsoft Office 2007. By leveraging enhanced capabilities, such as high availability mailboxes and advanced clustering, the FDA's Office of Information Management (OIM) intends to reach its ultimate goal of providing a more stable and highly available enterprise e-mail capability while simultaneously reducing the amount of system management and intervention by administrators. In addition to being highly available and scalable, the system must be secure and compatible with the existing Tumbleweed e-mail encryption and IronPort anti-spam and anti-virus products. Additional capabilities, such as instant messaging (IM) and wireless access via BlackBerry devices, will also be upgraded. The implemented solution will provide system upgrades to the FDA's enterprise e-mail infrastructure; migration to the target system; Tier 3 support for the call center, desktop technicians, end users; and the operations and management of all back-office systems related to e-mail.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the

individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system transports electronic mail. The email system is only a conduit for message traffic and is not designed to collect, store, share, or disclose PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 5/17/2011

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Science First [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/7/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-10-01-2000-00-202-072

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC Science First

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Steven Hubbard

10. Provide an overview of the system: SCIENCE FIRST is a virtual agency-wide science center, consolidating scientific information from across the entire agency. SCIENCE FIRST contains tools and applications to support the agency's initiative of enhancing science within the agency, the continuing goal of science-based regulatory decision-making, fostering collaboration and communication between agency scientists, and increasing awareness of FDA research accomplishments. The regulation that applies to this system is the Government Paperwork Elimination Act (GPEA).

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The system collects and disseminates science-related and other pertinent regulatory information such as skills resources, research projects, scientific and regulatory publications, links to training and knowledge enrichment sources, and scientific data sources. This information will be used to support the agency's initiative to enhance science within the agency, the continuing goal of science-based regulatory decision-making, foster collaboration and communication between agency scientists, and increase awareness of FDA research accomplishments.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/8/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Consolidated Infrastructure [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/7/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-02-01-01-0301-00-404-139

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC Consolidated Infrastructure

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Stephen Veneruso

10. Provide an overview of the system: FDA is moving towards long-term improvements in the structuring of IT services across centers which is aimed at facilitating greater integration in the delivery of programs and realizing significant cost savings. Efficiencies will be realized by consolidating the technology infrastructure services and in the standardization of how IT service is provided.

The consolidated infrastructure is described as local area networks, help desk and call center, voice and data services, desktop management and support, database and server management, and Intranet services.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Consolidated Infrastructure (CI) is not designed to collect, maintain, or disseminate information. The CI is intended to provide a secure and reliable computing environment in which other FDA applications and information systems can be hosted.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/8/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CVM Animal Drugs @ FDA (ADAFDA Greenbook) [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/1/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: TBD

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): CVM Animal Drugs @ FDA

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Margaret Zabriski

10. Provide an overview of the system: Animal Drugs@FDA is the main point of entry for accessing approved animal drugs information through the FDA publicly accessible website. Animal Drugs@FDA system is a publicly accessible internet application designed for read/only access to approved animal drugs information for use of both CVM and the public.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system only collects information on animal drugs and does not contain any PII

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/1/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA TurboEIR [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/1/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-1070-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-10-0002 and 09-10-0010 (Bioresearch Monitoring Information System)

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA ORA Turbo Establishment Inspection Report (EIR)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carol Stone

10. Provide an overview of the system: The Turbo EIR Field Agent application provides a standardized database of citations, and assists the investigator in preparation of the FDA Form 483 and the Establishment Inspection Report (EIR).

FDA field investigators annually conduct approximately 17,000 establishment inspections. A Food Drug and Cosmetic Act requirement of the inspectional process is to report (in writing) certain types of adverse observations to the management of the inspected firm at the conclusion of the inspection. About forty percent of all inspections result in the issuance of an FDA 483. The FDA 483 is the written report listing the adverse observations observed by the investigator.

The investigators must also generate a comprehensive narrative for each inspection. These narratives are known as Establishment Inspection Reports (EIRs) and are commonly prepared with word processing software. Turbo EIR Field Agent provides onscreen guidance to the investigator for preparation of the EIR. Turbo on the Web is a web browser-based application that allows FDA users to retrieve FDA 483 and EIR documents via the FDA intranet.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or

other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is shared with various compliance/management operational divisions (such as Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Devices and Radiological Health, Center for Veterinary Medicine) in the FDA that perform enforcement, analysis, and trending. The system shares updated telephone and address information with the MARCS Domestics application, this replaces a manual process performed by the investigator.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Turbo EIR collects data on FDA regulated and inspected establishments. The system collects business data in the form of professional contact information, establishment address and telephone number. Personally identifiable information collected is limited to the names of clinical research investigators (e.g., physicians) who participate in an inspection. In some instances, these names are used for Turbo EIR data searches with a linked system of records (Bioresearch Monitoring Information System, SORN number 09-10-0010). Clinical research investigator names are provided voluntarily or on occasion by demand of FDA.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Assigned an inspection, the investigator travels to the establishment to perform it. If the investigator observes adverse conditions they are linked to the FDA citation database in Turbo EIR Field Agent. Within Turbo EIR Field Agent the investigator is then able to provide specific information relating to each observation. When all observations and specifics are recorded Turbo EIR Field Agent prints the FDA 483. The investigator then meets with the management of the firm and explains the adverse observations recorded. At this point the firm's management has an opportunity to have their comments added to the FDA 483. At the end of the management meeting the investigator presents the final FDA 483 (with comments) to the firm's management and the inspection is complete. Afterwards the investigator using Turbo EIR Field Agent authors the Establish Inspection Report (EIR). An EIR is created for each inspection, even if a FDA 483 is not issued. The EIR is a comprehensive report of the inspection and contains information needed to support the Violation Letter process and of interest to FDA management. The above activities directly support the FDA's responsibility to regulate food, drugs and devices.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within Turbo EIR is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within Turbo EIR.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Fred Sadler

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/23/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA NCTR Research Support [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/1/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-1331-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA NCTR Research Support System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Beth Harrison

10. Provide an overview of the system: The Research Support System (RSS) is an IT resource used to collect and store data for toxicology studies. It collects subject and experiment data from the introduction of an animal into the NCTR environment by purchase or birth, through the experiment process, and concludes with the data collected from micro-pathological examination of its tissues. NCTR's mission is to conduct peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The RSS collects data required by toxicology studies. It collects animal data such as weights, food/water consumption, and clinical observations; it collects data such as compound, treatment group and route of administration; and it collects data about the environment in which the experiment takes place such as cage conditions and placements. It also collects gross- and micro-pathology data. These data are required to conduct peer-reviewed scientific research and for the analyses and scientific papers based on the research.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Fred Sadler

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/2/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA NCTR Research Management [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/1/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-1330-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA NCTR Research Management System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Beth Harrison

10. Provide an overview of the system: The NCTR's mission is to conduct peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs. This research includes in-vivo, in-vitro and in-silico experiments that consume significant NCTR resources.

In order to maximize return on investment, NCTR must manage its resources carefully. To do this efficiently and effectively, NCTR has implemented a protocol tracking and approval process and an activity based costing regimen which requires significant data collection and reporting. The Research Management System (RMS) provides the essential tools for gathering these data and for providing the necessary decision support mechanisms used to allocate available resources to new and ongoing research efforts. No PII is needed or collected.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The RMS collects data required by its protocol approval and tracking efforts as well as the data needed to conduct activity based costing functions. Types of data collected include protocol review and approval information, document production and publishing, cost factors, specific training requirements, FTE availability and resource (labor hour and dollar) costs estimated for and consumed in support of specific projects (protocols). Individual's names or other PII are not involved.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Fred Sadler

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/2/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA MARCS Imports - Operational and Administrative System for Import Support [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/1/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-08-01-1020-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA ORA Operational & Admin. System for Import Support (OASIS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: May Cheng

10. Provide an overview of the system: OASIS automated the re-engineered business processes which the FDA utilizes for making its admissibility determinations. These determinations are used to ensure the safety, efficacy, and quality of the foreign-origin products for which FDA has regulatory responsibility under the Federal Food, Drug and Cosmetic Act.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information is collected

initially from the Customs and Border Protection through their ACS system. All time spent reviewing commercial entry data, both on-screen and via paper entry documentation, are recorded as Entry Review. This includes checking regulatory status by accessing Center databases or FIARS, review of FD Form 2877s, Affirmation of Compliance Codes and their qualifiers, and review for data accuracy during Entry Review.

In addition, all time spent to make and record May Proceed decisions, regulatory recommendations such as Detention Requests (DTR) or Detention w/o Exam Requests (DER) and setting up Investigations exam/collect work assignments should be recorded as Entry Review. Any changes to transmitted data found to be inaccurate are made before setting up exam/sample assignments if possible. Such errors are then provided to the district personnel responsible for conducting filer evaluations.

In summary OASIS is a mission critical system that supports about 3500 FDA users throughout the US users on a 24/7 basis. It provides:

- An automated interface with US Customs Service systems
- Automated pre-screening processes
- Support for Entry-Reviewers and Compliance Officer review of regulated products, including computer-aided decision-making
- Maintenance of information for reporting decision-making
- Tracking and review of workflow

The OASIS information is shared with Dept. of Homeland Security, Customs and Border Protection (ACS), FACTS, ORADSS, and FDA Centers.

OASIS enables FDA to handle more efficiently and effectively the burgeoning volume of shipments (now over 8 million/year -- up by 50% in the last four years) of imported products, despite decreasing agency resources. It also maximizes the efficiency and accuracy of the import review process to ensure the safety of imports regulated by FDA on behalf of the American public.

OASIS automates a number of previously manual processes, provides more timely data and better data integrity to support decision-making. It also supports better workflow between the Entry Reviewers and Compliance Officers as well as an ability to monitor performance. No IIF information is being collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Fred Sadler

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/27/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA Recall Enterprise System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/1/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-08-01-1011-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA ORA Mission Accomplishment and Regulatory Compliance Services (MARCS) Recall Enterprise System (RES)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carol Stone

10. Provide an overview of the system: The MARCS Recalls system provides centralized and standard safety and health alerts and regulated product recall information internally at the FDA. Alerts and recalls are an effective method of providing alert notices to the public, and for removing or correcting consumer products that are in violation of the laws administered by the FDA.

The MARCS Recalls Intranet system is FDA's first agency wide Recall IT system. MARCS Recalls supports business processes for managed application reviews, workload management, investigative, compliance, and analytical operations, quality assurance and other critical initiatives (Manage and Conduct Compliance Work; Monitor Recall; Monitor Regulatory Actions; Negotiate Compliance Action; Support Regulatory Field Action; View Firm Information).

MARCS Recalls Intranet allows FDA personnel to create recall alerts, document recall actions, and to recommend a recall strategy. The system provides capabilities to close recalls when completed and to archive/retain recall records for future use. The system also provides a capability to post a subset of the recall information to the Internet (MARCS Recalls Internet) allowing the general public to view recall information. Although the posting of the data to the Internet database is active, the website accessibility is currently not made available for public access.

The MARCS Recalls Intranet application provides automated support for the daily operations of ORA Field Offices, Center Coordinators, and Headquarters to support the compliance and enforcement activities (Office of Enforcement) of FDA's Office of Regulatory Affairs (ORA).

MARCS Recalls Intranet is an online system that also integrates with other strategic systems at the FDA to provide additional support and information for the recall. MARCS Recalls Intranet system integrates with the "FIRMS" data (holds shared information for the Field Accomplishment and Compliance Tracking System (FACTS); Operation Administrative System for Import Services (OASIS)), as read only, and allows for information to be stored with the recall record.

MARCS Recalls Intranet also allows for a precedent search for (CDRH) recalls requiring Health Hazard Evaluation (HHE) information. The MARCS Recalls Intranet supports approximately 50 to 100 concurrent users (per day). MARCS Recalls Intranet has approximately 512 FDA Intranet users that are recorded in the application users, across the U.S.

The FDA's Office of Regulatory Affairs (ORA) is focused on assuring that manufacturing firms comply with FDA regulations in order to achieve consumer safety and health protection. The FDA's Investigations Operations Manual 2003 states that "ORA's mission is to achieve effective and efficient compliance of regulated products through high quality, science-based work that results in maximizing consumer protection." Within ORA, the Recall Operations Staff (ROS) in the Office of Enforcement (OE), Division of Compliance Management and Operations (DCMO) serves as the Agency's focal point for all safety and health alerts, and product recall activities. ROS is also responsible for providing policy, procedure, and direction to the FDA field and Center recall operations as dictated by the Food, Drug and Cosmetic (FD&C) Act.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Almost all of the data

captured through the RES application is non-personal and can be grouped into the follow categories:

- Firm information
- Product information
- Center-specific information
- Recall Event information
- Recall Recommendation information
- Recall Classification information
- Recall Summary and Termination information

PII is not collected on this system.

The internal aspect of the system uses the business contact information (names and email addresses) of the individual FDA employees who create or work with the records in the RES application. These needed pieces of PII come from the FDA's FACTS database, which is accessed through the individual's RES login codes. The user's name and email provides access to the user's profile information record in the RES database. These records contain information regarding each user's role, and the FDA Center with responsibility for the over sight of the recall activity.

Coordinator names are also displayed or included for data collection needs of the recall event, work flow processing, and for the application to submit proper notifications. In addition, comment fields are available within the system in which the users will add necessary information, when applicable, in order to process or ensure information is provided for "recall" requirements.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - PII is not collected on this system.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A - PII is not collected on this system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Fred Sadler

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/2/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN CFSAN Adverse Event Reporting System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/31/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-4100-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Yes. A System of Records Notice (SORN) is currently in development with system number to be assigned.

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CFSAN Adverse Event Reporting System (CAERS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Debra Street

10. Provide an overview of the system: CAERS is part of CFSAN's Strategic Plans - Strategic Goal 3.5: Reduce the health risks associated with food and cosmetic products by preventing human exposure to hazards, monitoring product quality, and correcting problems that are identified.

CFSAN is responsible for assuring a safe and wholesome food supply as well as safe cosmetics for the United States' consumers. As part of this mission, CFSAN performs post-market surveillance (CAERS) by collecting and monitoring adverse events resulting from the use of the following:

- cosmetics,
- traditional foods,
- food and color additives,
- Generally Recognized as Safe (GRAS) ingredients,
- special nutritional products including dietary supplements,
- medical foods, and
- infant formulas.

While a small portion of these products have mandatory pre-market approval, pre-market notification, and/or post-market surveillance requirements, most of these products, notably dietary supplements, have no such requirements. CFSAN's primary source of information about

these products and post-market surveillance is collected through voluntary adverse event reporting handled by CAERS.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Internal FDA systems

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The mission of the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) is to assure the safety and wholesomeness of the nation's dairy products, plant foods, beverages, seafood, dietary supplements, cosmetic products, infant formula, medical foods, food and color additives, and all ingredients that come into contact with foods (CFSAN regulated Products). Among CFSAN's priority activities supporting this mission is performing post-market surveillance including but not limited to collecting, monitoring, and analyzing adverse event reports and product complaints, which are alleged to be related to CFSAN regulated products. Virtually all of reports of the adverse events and product complaints are voluntary submissions from consumers, health professionals, and other interested parties. The very rare exception to voluntary submission is the mandatory reporting required for firms that manufacture infant formula when a death of an infant has been associated with their product. Reports are captured and processed and enter the CFSAN Adverse Event Reporting System (CAERS) through several routes (FDA's Field Accomplishments and Compliance Tracking System (FACTS), FDA's MedWatch Program, and direct mail, e-mail, or phone messages to CAERS). Voluntary IIF information may be included in the system. However, records are not retrievable by a typical IIF; instead, an agency-assigned CAERS case number is given to the case when information is entered into CAERS. The CAERS data is used as a basis for enforcement and regulatory action on CFSAN regulated firms and products to help perform the mission described above.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Controls and safeguards are in development in tandem with the System of Records Notice.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/3/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Low Acid Canned Foods [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/31/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-0505-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CFSAN Low Acid Canned Foods (LACF)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Mignogna

10. Provide an overview of the system: The LACF system gives low acid canned foods processors the ability to register data in accordance with CFR Title 21, Parts 108.25, 108.35, 113, and 114. In Phase I, only CFSAN and FDA Field personnel involved in enforcement activities had access to the software and data. The Phase II implementation provides Domestic industry the ability to submit products' processes as well as monitor all submissions. When full implementation takes place, all foreign and domestic LACF facilities will have the ability to engage in online access and monitoring of a facility's products' processes.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: In accordance with CFR Title 21, Parts 108.25, 108.35, 113, and 114, the data collected is reviewed by technical staff to provide proof that the LACF-related product is commercially sterile to prevent a potential health hazard.

The CFSAN and FDA staff use this data to enforce CFR Title 21, part 108 regulations.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/1/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN Voluntary Cosmetics Registration Program [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/31/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-0505-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: OMB 0910-0027 (Exp. 11/30/2007) and OMB 0910-0030 (Exp. 12/31/2008)

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CFSAN Voluntary Cosmetics Registration System (VCRP)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donald Havery

10. Provide an overview of the system: The Voluntary Cosmetics Registration Program (VCRP) system is a web-based system allowing the cosmetics industry to obtain a registration number for manufacturing establishments and cosmetic product formulations by electronically requesting it, i.e. completing Form 2511, 2512/12a, or 2514, over the Internet.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The Voluntary Cosmetics Registration Program system is a web-based system allowing the cosmetics industry to obtain a registration number for manufacturing establishments and cosmetic product formulations by electronically requesting it using their web browser. Once the registration number is approved, they will also be able to submit and edit product and ingredient information in a similar manner, i.e. using web-based Forms 2512 and 2512a.

The program is voluntary. Companies are requested to provide the physical location of their manufacturing establishments so they may be inspected for good manufacturing practices. Participants are also requested to provide information on their cosmetic product formulations which aids the agency in determining what ingredients are being used in cosmetic products and what preservative systems are being used to protect the integrity of the product.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Daivs

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 9/1/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CVM Corporate Document Management System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/31/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-09-02--1020-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CVM Corporate Document Managment System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dennis delRosario

10. Provide an overview of the system: CDMS serves as a secure centralized repository for key documents. The system provides a single access point to search, retrieve, and annotate policy and regulation documents, labels and CVM-generated review documents, and letters related to the sponsor submissions.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information consists of

policy and regulations documents, labels, and CVM generated review documents and letters related to sponsor submissions. Information does not contain IIF and is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Tim Stitley

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: John R. Dyer

Sign-off Date: 8/15/2007

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA MARCS Domestic - Field Accomplishments and Compliance Tracking System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/31/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-08-01-1010-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-10-0010

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA ORA MARCS Domestic - Field Accomplishments and Compliance Tracking System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Suet Man

10. Provide an overview of the system: FDA's inspection process, managed by FACTS, is responsible for the health and safety of the American Public by providing support to the overall FDA's mission of promoting and protecting the public health by helping safe and effective products reach the market, and monitoring products for continued safety after they are in use. Legislation authorizing this activity is the Food Drug and Cosmetic Act.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Firm data which may include Physician Names (as Firm entities) is contained within FACTS and used by many agencies within the FDA for many purposes including Firm inspections.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The FACTS system contains data about commercial firms and their business relationships, data, FDA decisions, manpower, procedures, establishments, commerce, compliance, enforcements, products, consumer complaints, and FDA organizations.

There are Firms that are Physician entities represented by their Physician Name. These names may be considered IIF.

The FACTS database provides information on FDA performance to Congress and the OMB, and supports the Drug industry's PDUFA initiatives. This system also presents rapid review of current and past fieldwork assignments, results, and time/cost to accomplish in the Agency mission areas of regulation, surveillance, and compliance.

The system provides support to the overall FDA's mission for promoting and protecting the public health by helping safe and effective products reach the market, and monitoring products for continued safety after they are in use.

FACTS shares collected information with the following systems:

Lab data exchange between FACTS-OASIS (ORA), Data to FACTS Reports; OPAS (ORA), Assignment data to Turbo EIR (ORA),

Firm profile data to ORA/DCIQA (Intranet/Internet), Lab data to eLEXNET (ORA, CFSAN), Complaints & Adverse event data to CAERS (CFSAN),

Firm profile data feed to CDER,

Pre-approval inspection data exchange with EES (CDER),

Firm data to eDRLS (CDER),

Inspection data from MPRIS & CASS (CDRH)

The primary users of FACTS are FDA organizations (see above) that enter, update, retrieve, and otherwise manipulate the data contained in the FACTS database with the ORA Field Offices staff being the principal suppliers of FACTS data. The Centers then make extensive use of FACTS to communicate with the Field.

The secondary users of FACTS include organizations and individuals' external to the FDA that contributes industry information to the FACTS database. These include consumers, health care providers, state partners, state public health agencies, and other Federal agencies.

FACTS has built-in controls to grant or modify access to the relevant data based on the user role and District he or she belongs to with FACTS end users having only 'read only' access to data from other district offices.

For the FACTS/eSAF system there are three primary security zones. The three zones are 1) the Internet, 2) the Service Area Network, or Demilitarized Zone (DMZ), and 3) the Intranet or "inner core". This approach separates the functions of "border control," "identification and authentication," and "access control."

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes currently in place.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within RES is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within RES.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: John R. Dyer

Sign-off Date: 8/22/2008

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Appian Business Process Management [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/16/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC Appian Business Process Management

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Janie Ma

10. Provide an overview of the system: The Appian Business Process Management (BPM) suite facilitates the deployment of robust processes, collapsing time to value for process improvement initiatives. The Appian BPM Suite is a web-based BPM platform, delivering the ease of use, comprehensive features and flexibility required to accelerate process improvement. By simplifying process collaboration between business and IT, Appian empowers business decision makers, while allowing IT to easily extend, integrate and personalize its BPM applications.

Appian BPM provides the following features:

* Collaborative User Portal-- Appian provides process designers with complete control over the creation of interfaces for end-users, delivering personalized content, shared work queues, and aggregated content from related systems.

* Rapid Application Deployment-- Rapid application development is facilitated by Appian's BPMN modeling, collaborative design, repository of re-usable components, and rich UI controls.

* Real-time Process Architecture-- Appian's real-time process architecture delivers streaming data to dashboards and process rules which monitor all aspects of a process, including highly flexible reports, access to all process data, fast rule processing, and high scalability.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Appian BPM--planned to go operational in the migration to the FDA data center in Ashburn, VA--will host several FDA applications. In this sense, Appian BPM will act as a general support system to the hosted applications and will be considered as a component of the FDA Consolidated Infrastructure. The hosted applications will be able to inherit certain security controls provided by the Appian BPM platform. These may include audit records generation, access control, and identification and authentication of application users.

The Appian BPM platform utilizes a built-in Apache HTTP server and JBoss Application Server with Apache Tomcat Servlet Containers. Information will flow from the end user's web browser to the Apache HTTP server. The HTTP server will direct the information flow to the applicable application hosted in the JBoss Application Server container. Appian BPM also incorporates a built in proprietary database, called the "K Database."

Appian BPM will host several FDA applications. These hosted applications will maintain their own information collection and flow based on functional business requirements. The information collection of the hosted applications is beyond the scope of this security assessment of the Appian BPM.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within Appian BPM is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within Appian BPM.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/27/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC User Fees System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/6/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-01-01-4140-00-402-125

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): UserFee was only recently discovered to be subject to the Privacy Act. A SORN is being created, but is not completed.

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC User Fee System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Amy Kramer

10. Provide an overview of the system: The User Fee System is a component system of the Financial Enterprise Solutions (FES) Mission Critical computer security classification investment. The system application utilizes various modules of the Oracle eBusiness Suite, v.11.5.9.

The system was developed to respond to the legislative needs of:

Prescription Drug User Fee Act of 2003

Medical Device User Fee and Modernization Act of 2002

Animal Drug and User Fee Act of 2003

Mammography Quality Standards Act

Internal users access the system through the firewall-shielded secure FDA network. Thousands of external industry users access the system via the Internet through a back and front-end, firewall-shielded sub-network in a demilitarized zone. System servers are located in the FDA Network Control Center on the second floor of the Parklawn building in Rockville, Maryland.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): All information collected is required to exchange by the federal government to facilitate payments required by the User Fee legislation. The data collected is the minimum necessary to complete the coversheet and billing processes.

Internal users access the system through the firewall-shielded secure FDA network. Thousands of external industry users access the system via the Internet through a back and front-end, firewall-shielded sub-network in a demilitarized zone. System servers are located in the FDA Network Control Center on the second floor of the Parklawn building in Rockville, Maryland.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The User Fee System collects data related to transactions for which external industry users must pay fees. Such transactions involve user fees associated with:

- Prescription Drug User Fee Act of 2003
- Medical Device User Fee and Modernization Act of 2002
- Animal Drug and User Fee Act of 2003
- Mammography Quality Standards Act

For internal federal users, the User Fee System collects specifically identifiable information about the names and email address. The records are of employees responsible for accessing Oracle Applications as approved by the account approval process.

For external industry, the User Fee System collects business identifiable information about name, address, telephone numbers, email addresses, DUNS, waiver information and Federal Employee Identification number.

All information collected is required to exchange by the federal government to facilitate payments required by the User Fee legislation. The data collected is the minimum necessary to complete the coversheet and billing processes.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original

collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes in place.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within User Fees is protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within User Fees.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/27/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDER Adverse Event Reporting System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/1/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-03-01-1010-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDER Adverse Event Reporting System (AERS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jeanette Somerville

10. Provide an overview of the system: Drug Safety (Adverse Event Reporting System-AERS) is a computerized information database designed to support the FDA's post marketing safety surveillance program for all approved drug and therapeutic biologic products. The ultimate goal of Drug Safety (AERS) is to improve the public health by providing the best available tools for storing and analyzing safety reports.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The system does not require collection of any IIF data for successful submission. However, some physicians, hospitals, or public may voluntarily submit IIF data, for example, social security numbers and patient names.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Voluntary reporters have the option to report or not, to include their IIF or not, and if included, to select a check box requiring that the data be redacted when shared with anyone else. There will be a consent page on spontaneous reports explaining the process to the reporter. Mandatory reports are created by the importer/manufacturers and include what IIF may be known to them. They can likewise express the patient's consent to sharing IIF through the same checkbox method. The consent form will specifically include all future uses, and will direct the user to the FDA web page that will detail any change in expected use of the data.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The security plan as it relates to the implementation has not yet been written, but there will be non-functional requirements that mandate such security. There is an administrative and technical control by use of password and user identification and the system will be located at a secure facility.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/27/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CFSAN CFSAN Automated Research Tracking System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/10/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-0202-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CFSAN Automated Research Tracking System (CARTS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mark Wirtz

10. Provide an overview of the system: The CFSAN Automated Research Tracking System (CARTS) tracks all CFSAN research projects, including Counter-Terrorism projects.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1)CARTS records all information on research conducted within CFSAN and in collaboration with external organizations from scientists and managers.

2)Name is used to identify collaborators

3)Name and affiliation

4)Mandatory

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/31/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA ORA Electronic Laboratory Exchange Network [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 4/26/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-02-1070-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA ORA Electronic Laboratory Exchange Network (eLEXNET)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tim Rigg

10. Provide an overview of the system: The Electronic Laboratory Exchange Network (eLEXNET) was developed to facilitate secure information sharing among public health partners and collaboration among food safety experts. eLEXNET provides food safety officials with access to food test results for analytes of concern at the detail level and at the product or product industry level.

eLEXNET is a seamless, integrated, secure network that provides multiple federal, state and local government agencies engaged in food safety activities with the ability to compare, communicate, and coordinate findings in laboratory analyses. The system enables U.S. health officials to assess risks, analyze trends, and identify problem products. It provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: eLEXNET currently allows food safety laboratories at all levels of government (federal, state, local) to share real-time food safety sample and analysis data on selected microbiological analytes. eLEXNET receives sample status and sample analysis summary, laboratory analytical methods and results, and laboratory conclusions from other systems within FDA, as well as from participating laboratories. All data collections are necessary to meet the goals of this system. No Personally Identifiable Information is collected or stored in the eLEXNET system. Prior to obtaining access credentials, when laboratories agree with and sign the written Memorandum of Understanding (MOU), they are informed of the data collection process.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/31/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Agency Information Management System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 4/19/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-10-01-1010-00-404-142

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-10-0004 (FDA) Communications (Oral & Written) with the Public, 09-90-0058 (HHS) FOI Case Files and Correspondence Control Index, OGE-1 (Office of Government Ethics) Financial Disclosure Reports & Other Ethics Programs, OGE-2 (Office of Government Ethic

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC Agency Information Management System (AIMS)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rosie Whitcraft

10. Provide an overview of the system: AIMS provides administrative tracking and electronic storage for several agency functions. The core data within AIMS is pulled from the agency ASAP and EASE system for staff, contractor, and organizational data required for the applications. The core also contains any information that is shared by two or more of the AIMS modules. The modules are Correspondence (both internal generated and received from external sources), Freedom of Information (FOI), Federal Register (FR), Dockets Management, Advisory Committee, Ethics, Passports, Records Case Management, Office Moves, Awards and Interagency Consult Reviews. The system also has a records management application for all records tracked in the system.

The module for Administrative Tracking and Electronic Document Storage of FOI requests, responses, and related correspondence is authorized by the Freedom of Information Act, (FOIA) 5 U.S.C. 552. The module for Ethics records is authorized by the Ethics in Government Act (PL 95-521) and the Ethics Reform Act of 1989, as amended (PL 101-194). The Civil Service Act authorizes the module for Security Clearances. The Federal Advisory Committee Act authorizes the module for Advisory Committee Records.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the

individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: FDA receives approximately 24,000 FOI requests per year. A tracking system is required to monitor the processing of requests. In addition the FOIA and the Ethics in Government Act have annual reporting requirements that are based on information collected in the system. The Passport staff is responsible for obtaining and maintaining the government-issued passports for all FDA personnel.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is obtained from correspondence submitted by the FOI requesters and individuals that correspond with the agency or comment on a Federal Register notice. FDA's Public Information Regulations at 21 CFR Part 20 inform the public of the procedures for submitting FOI requests. Federal Register notices inform individuals of the procedures for commenting on a notice. In the case of security clearances and ethics, when an individual comes to work at FDA as an employee or contractor they are required to complete forms requesting the information. Forms contain notification statements informing the individuals of the purpose for collecting the information and the authority for collecting the information.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information contained within AIMS is

protected by several layers of administrative, physical, and technical controls in accordance with policies and regulations from the FDA, NIST, and OMB. All applicable security controls are reviewed on a periodic basis to ensure that they are implemented correctly, operating as intended, and producing the desired result of protecting all information within AIMS.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/31/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDER Substance Registration System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 4/12/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-02-01-0303-00-110-032

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDER FACTS@FDA

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Gini Khalsa

10. Provide an overview of the system: FACTS@FDA--which is comprised of the Substance Registration System (SRS)--combines the features of the Substance Registration System (SRS) and Center Ingredient Dictionary (CID) application within a modern application environment that efficiently integrates software from MDL Information Systems within a J2EE environment. This system provides enterprise-wide integration with other FDA applications.

SRS enables FDA to efficiently, effectively, and reliably maintain unique identifiers for substances in drugs, biologics, foods, and devices, and make them available for use in health information systems.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Within the proposed FDA FACTS@FDA project, the Agency will use the system and use the collected information as listed below:

Manufacturers submit labeling content and content changes to FDA in a standard electronic format.

FDA receives labeling and listing changes from manufacturers and imports the information into an electronic labeling repository.

FDA processes the labeling content and changes using SPL review and workflow management tools that access the electronic repository.

FDA exports up-to-date SPL to the NLM on a daily basis.

NLM disseminates the medication information to healthcare information suppliers who make it available to the public.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/30/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CVM Corporate Database Portal [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/5/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-09-02--4070-00-110-246

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CVM Corporate Database Portal

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Margaret Zabriski

10. Provide an overview of the system: CDP is the main point of entry for accessing user applications and is located within the FDA's enterprise architecture web portal. The CDP contains customized applications that support the Office of New Animal Drug Evaluations (ONADE), Office of Surveillance and Compliance (OSC), Office of Management (OM), Office of Research (OR), Office of Minor Use and Minor Species Animal Drug Development (OMUMS), and the Document Control Unit (DCU). The CDP provides a single point of entry for users to access various applications that support their work activities.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: STARS provides the CVM with a comprehensive database for ensuring the safety of animal drugs and feeds. STARS is a cumulative database of all submissions, both active and inactive, comprising a drug submission application of both investigational and commercially marketed drugs for animal use. STARS includes information supporting the implementation of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA).

Information is exchanged between STARS and Oracle Financials for ADUFA and AGDUFA via database links. CVM Personnel register sponsors of applications and sponsors of marketed veterinary products directly in Oracle Financials, and the STARS dictionary of sponsors is updated. The CVM UserFee evaluation officer grants fee waivers to applicants in STARS, and the waiver information is automatically transferred to corresponding tables in Oracle Financials. When an application coversheet is received at CVM, and information about the submission is entered into CDP, data about the evaluated coversheet is inserted directly into a table in the Oracle Financials database. Billing information for annual fees is maintained in STARS, and the process of generating invoices draws upon this data through the database link. The invoice process in Oracle Financials for ADUFA and AGDUFA updates the billing tables in CDP.

The Office of Surveillance and Compliance (OSC) BIMO Team administers three compliance programs: Good Laboratory Practices (GLP); Sponsors, Contract Research Organizations, and Monitors (Sponsor/Monitor); and Clinical Investigators (CI). The BIMO Team requests inspection assignments under these programs and when the inspections have been assigned and completed, the Establishment Inspection Reports (EIR) are forwarded to the BIMO Team. The BIMO Team tracks activities from requesting the inspection assignments to final EIR classifications and close outs. The BIMO module provides the ability to effectively track and report on key BIMO activities.

The OSC monitors marketed animal drugs, food additives and veterinary devices to assure their safety and effectiveness and enforces compliance with the animal drug regulations. OSC also tracks and reports on Drug Listing information (e.g., animal drug manufacturer's establishments, distributors, labeling data, ingredients and trade names). The DPL module compiles this information for all animal drugs that are in commercial distribution or have been discontinued.

The DERS module allows reviewers to monitor Adverse Drug Experience (ADE) reports, both original and follow-up reports on Form FDA 1932; quantity marketed reports which may or may not be broken down by distributor; animal drug product labels; and, other items (e.g., bibliographies, promotional/advertisement pieces, etc.).

ATR aids employees at all levels of CVM in managing the use of their time and monitoring the progress of their work. Specifically, the ATR System provides CVM managers with the ability to capture real-time data for use in strategic and operational planning, management information reports, budget requests and justifications and/or evaluation, cost and trend analyses, and user fee negotiations and/or management activities.

CDLM incorporates the Compliance reference documents into the Corporate Document Management System (CDMS). It provides users with the ability to assign submission type codes and numbers in STARS in order to track the reference documents.

The NARMS is a new module under the CDP that supports the CVM Office of Research in tracking and monitoring antimicrobial resistance patterns in retail meat samples. The NARMS module allows users to view, enter and update data, execute queries and generate reports based on the retail meat samples.

The purpose of the Minor Use and Minor Species (MUMS) Index File System (MIFS) is to support CVM in its efforts to implement and manage the mandated activities of the MUMS Act of 2004. The MIFS provides

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Tim Stitley

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/30/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA CDER Electronic Common Technical Document [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/2/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-04-02-0205-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA CDER Electronic Common Technicial Document (eCTD)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Angela L. Williams

10. Provide an overview of the system: eCTD stores electronic New Drug Applications (NDA) submission files and metadata about submissions, allowing reviewers to access submissions via a web-based interface.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDR/eCTD is a Major Application (MA) developed to comply with the mandates set forth in the Prescription Drug User

Fee Act (PDUFA) and Food and Drug Administration Modernization Act (FDAMA) to reduce the review time required to obtain approval to market new drugs in the United States (U.S.), track the status and progress of each application, and accept regulatory submissions in an electronic format.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 8/31/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Clarity [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/29/2010

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA Clarity

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Heidi Snyder

10. Provide an overview of the system: This project will enable a robust electronic COTS software to be deployed that is capable of tracking, storing and reporting on IT projects, contracts, assets, and other information. Data stored can be managed by defined workflow/processes that provides oversight and approval mechanisms. Data can be mined to provide a variety of reports either pre-defined or customized using Business Objects that is bundled with the Clarity product.

· To effectively collect and manage FDA project information in a central repository using the enterprise portfolio management system, Clarity.

· To automate and standardize FDA business and IT processes using role-based assignments and stage gate review support

· To provide real-time [FME1] visibility into the status, budget, schedule, dependencies, demand points and other information related to FDA projects

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Clarity will capture and store project, contract and asset management information.

Clarity will not collect any PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Frederick J. Sadler

Sign-off Date: 4/9/2010

Approved for Web Publishing: Yes

Date Published: August 30, 2011

06.3 HHS PIA Summary for Posting (Form) / FDA OC Facility Management System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2009

2. OPDIV Name: FDA

3. Unique Project Identifier (UPI) Number: 009-10-01-10-02-1040-00-401-119

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): FDA OC Facility Management System

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Don Demers

10. Provide an overview of the system: Facility Management System is an integrated solution to further provide better services/information to all Centers and ORA on any facility related issue, such as designing, planning, leasing, or operation.

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system will allow the Office of Real Property Services, Office of Shared Services, to maintain a comprehensive

database to better serve all Centers/ORA on their needs related to space design, planning, and any alteration projects within the Food and Drug Administration.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?: No

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lori Davis

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: John R. Dyer

Sign-off Date: 8/22/2008

Approved for Web Publishing: Yes

Date Published: August 30, 2011
